

**IN THE CLAIMS:**

1. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a protective device including a pad to be applied to the body part to be protected where the body part and bone structure to be protected may include a bony prominence tending to concentrate the weight (W) of the body part over a small area (A1) and to increase the produce a pressure (P1), which is equal to  $W/A1$ , at the interface between the bony prominence and its corresponding soft tissue layer, and wherein P1 when applied for a time t1 tends to cause a pressure ulcer to develop in the body part associated with the bony prominence ;

said protective device pad having: (a) an a top, inner, surface subtending the bony prominence and conforming to the body part containing the bony prominence to which it is applied; and (b) having an a bottom, outer, surface suitable for making contact with the support structure for increasing the area over which the weight at the bony prominence is distributed; and said protective device pad including material extending between the inner and outer surfaces having a softness and giving thickness to the pad; the area of the top and bottom surfaces and the thickness of the pad, as well as the softness of the pad material, being selected to be a function of the shape, size and weight of the bony prominence and body part to be protected and of sufficient thickness and softness to distribute the weight concentrate at the bony prominence of the body

~~part applied to its inner surface~~ (a) over an extended area which is greater than A1; and (b) over an extended volume in order to reduce the pressure exerted at the interface between the ~~bone structure~~ bony prominence and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure; and

~~wherein the bone structure of the body part to be protected includes a bony prominence tending to concentrate the weight of the body part over a small region tending to increase the pressure at the interface between the bony prominence and its corresponding soft tissue layer, and wherein the protective device pad is shaped to enclose~~ (a) the portion of the body part containing the bony prominence and (b) the bony prominence; and the ~~protective device pad~~ being shaped to extend continuously between ~~the body part and the~~ area subtending the bony prominence ~~containing the bony prominence~~ and the support structure to increase the effective surface area ~~and volume~~ over which the concentrated weight at the bony prominence is distributed in the space between the bony prominence and the support surface in order to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer to a level which is substantially less than P1 and less than the pressure that would cause a pressure ulcer to develop in that part of the body, within a time t1.

2. (currently amended) The prosthesis as claimed in claim 1, wherein the top surface of the pad is sculpted to conform to the shape of the body part to be protected for enabling the body part containing the bony prominence to be positioned within the sculpted region and for increasing the surface area over which the weight of the body part and the bony prominence is distributed; wherein, in the absence of the protective device, the concentrated weight at the bony prominence due to the bone structure and its corresponding overlying body part is defined as **W** and wherein, when the body part is in direct contact with the support surface, the weight **W** is distributed over a small area, defined as **X-A1**, at the interface between the bony prominence and its corresponding soft tissue layer resulting in a pressure  $P1$  equal to ~~**W/X**~~  $W/A1$  at the interface between the bony prominence and its underlying soft tissue layer; and wherein the ~~protective device~~ pad enclosing the body part containing the bony prominence, located between the body part and the support surface, is shaped to cause ~~causes~~ the effective area between the bony prominence and its associated soft tissue layer over which the weight **W** is distributed to be equal to ~~**[Y-] A2**~~, where ~~**[ Y ]A2**~~ is greater than ~~**[X-] A1**~~, whereby the resulting pressure between the bony prominence and its underlying soft tissue layer is equal to  $P2$ , which is equal to ~~**[W/Y-] W/A2**~~, where  $P2$  is less than  $P1$ , and  $P2$  is less than a critical value of pressure which would tend to cause ulcers in the body part within the time  $t1$ .
3. (currently amended) The prosthesis as claimed in claim 1 wherein the ~~protective device~~ pad material is one of an elastic material, a compliant

mushy foam, a generally compliant material and a mesh material; and  
wherein the bottom surface of the pad shaped conforms generally to the  
surface of the support structure to increase the area over which the weight  
at the bony prominence is distributed as a function of the distance from  
the bony prominence to the support surface.

4. (currently amended) The prosthesis as claimed in claim 1 wherein the  
pad material is of the type which enables the top, inner, surface to conform to,  
and surround, the body part containing the bony prominence and also enables  
the bottom surface of the pad to conform generally to the surface of the support  
structure for enabling the body part when positioned within the protective device  
pad conforms to the body part to which it is applied and is shaped for causing to  
distribute the weight concentrated at the bony prominence ~~to be distributed~~ over  
a larger area than A1 at the interface between the bony prominence and the soft  
tissue layer and over an area ~~and volume~~ which increases as the distance from  
the bony prominence to the support surface increases; ~~and~~

~~wherein the body part to which the protective device pad is mounted~~  
~~applied can be freely moved in any direction .~~

5. (currently amended) The prosthesis as claimed in claim 4 wherein the  
thickness of the ~~protective device~~ pad may be selectively increased to  
decrease the pressure at the interface between the bony prominence and the  
corresponding soft tissue layer; and

wherein the body part to which the pad is applied can be freely moved in  
any direction..

6. (currently amended) The prosthesis as claimed in claim 1 wherein the ~~protective device includes a pad and wherein the thickness of the pad may be selectively increased by adding layers to its outer surface.~~ is at least one quarter (1/4) of an inch, and wherein the length of the pad may range from one quarter (1/4) of an inch to more than six inches and the width of the pad may range from one quarter (1/4) of an inch to more than six inches.

7. (currently amended) The prosthesis as claimed in claim 1, wherein the body part to be protected is includes at least one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the ~~protective device~~ pad conforms to the shape of the body part containing the bony prominence of its respective body part and its outer surface is generally conformable to the support surface.

8. (cancelled) The prosthesis as claimed in claim 7, wherein the outer surface of the protective device includes a hard outer shell.

9. (cancelled) The prosthesis as claimed in claim 7, wherein the outer surface of the protective device includes a hard outer shell for insulating the body part from the effects of the support structure.

10. (cancelled) The prosthesis as claimed in claim 9, wherein the inner surface of the protective device also includes a hard inner shell.

11. (currently amended) The prosthesis as claimed in claim ~~3~~1, wherein the ~~[protective device includes a]~~ pad which is made of a soft material whose outer surface is generally conformable to varied support structures and having sufficient thickness of at least one quarter (1/4) of an inch to reduce the

pressures developed within the body part to enable the body part to which the pad is applied to rest on the support structure for an extended period of time without developing a pressure ulcer between the bony prominence and the corresponding soft tissue layer of the body part.

12. (previously amended) The prosthesis as claimed in claim 11, wherein the portion of the outer surface of the pad making contact with the support structure conforms generally to the shape of the support structure.

13. (currently amended) The prosthesis as claimed in claim 4 wherein the ~~protective device includes a pad and the~~ inner surface of the pad conforms to the shape of a heel and extends from the arch to ~~above~~ the ankle region and wherein the portion of the outer surface of the pad making contact with the support structure conforms generally to the shape of the support structure.

14. (currently amended) The prosthesis as claimed in claim 13, wherein the pad is fitted to be worn by a user and to cover an area ranging from the arch to at least the ankle region of a user.

15. (currently amended) The prosthesis as claimed in claim [13] 1, wherein the body part to be protected is the heel and wherein ~~portion of the pad extending~~ extends beneath the foot and the heel and extends the full width of the foot and the heel and is generally of cylindrical shape.

16. (currently amended) The prosthesis as claimed in claim [13] 1, wherein the pad is shaped like a semi-cylindrical sleeve located behind the ankle and leg and extending from below the foot to above the ankle.

17. currently amended)The prosthesis as claimed in claim [13] 1, wherein the inner portion of the pad extends around the bottom portion of the foot and ankle region and a portion of its shape may be one of the following: rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and a combination thereof.

18. (currently amended ) The prosthesis as claimed in claim 7, wherein each ~~protective device~~ pad includes means for securing the ~~device~~ pad to its corresponding body part.

19. (currently amended) The prosthesis as claimed in claim 3 wherein each ~~protective device~~ pad is placed around its corresponding body part so as to protect the body part regardless of the orientation of the body part on, or off, the support structure.

20. (currently amended) The prosthesis as claimed in claim 4 wherein the ~~protective device~~ pad is shaped to redistribute weight from the area of the bony prominence to other portions of the body part.

21. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:  
a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support

structure; and said protective device having sufficient thickness and softness to  
distribute the weight of the body part over an extended area and volume to  
reduce the pressure exerted at the interface between the bone structure and its  
corresponding soft tissue layer, across the corresponding soft tissue layer and at  
the interface between the corresponding soft tissue layer and the corresponding  
outer skin layer and between the corresponding outer skin layer and the support  
structure; and ~~The prosthesis as claimed in claim 1,~~ wherein there is included  
between the outer skin layer and the inner surface of the protective device at  
least one of the following:

- a- a layer of dressing;
- b- a layer of medicated dressing;
- c- a layer of hydrocolloid dressing;
- d- a layer of hydrocolloid dressing containing medication including  
at least one of an antibacterial, anti-inflammatory, anti-fungal,  
and anti-pain substance;
- e- a layer of hydrogel;
- f- a layer of hydrogel dressing containing medication including at  
least one of an antibacterial, anti-inflammatory, anti-fungal, and  
anti-pain substance;
- g- a thin film dressing;
- h- a thin film dressing containing medication including at least  
one of an antibacterial, anti-inflammatory, anti-fungal, and anti-  
pain substance;



- i- a layer of gauze dressing;
- j- a layer of gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- k- a layer of non woven-dressing;
- l- a layer of non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- m- a layer of foam dressing;
- n- a layer of foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- o- a layer of material adapted to absorb any excess moisture and drainage;
- p- a layer of material which exhibits moisture vapor permeability for removal of excess moisture; and
- q- a layer of material which exhibits permeability to air for enabling air circulation for removing excess heat and moisture; and
- r- a layer of material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

22. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume to reduce the pressure exerted at the interface between the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure; and ~~The prosthesis as claimed in claim 1,~~ wherein the protective device includes at least one of the following:

- (a) a dressing;
- (b) a medicated dressing;
- (c) a hydrocolloid dressing;
- (d) a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (e) a hydrogel;

- (f) a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (g) a thin film dressing;
- (h) a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (i) a gauze dressing;
- (j) a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (k) a non woven-dressing;
- (l) a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (m) a foam dressing;
- (n) a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (o) a material adapted to absorb any excess moisture and drainage;
- (p) a material which exhibits moisture vapor permeability for removal of excess moisture; and
- (q) a material which exhibits permeability to air for enabling air circulation; and

(r) a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

23. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume to reduce the pressure exerted at the interface between the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure;

wherein the bone structure includes a bony prominence tending to concentrate the weight of the body part over a small region tending to increase the pressure at the interface between the bony prominence and its corresponding soft tissue layer, and wherein the protective device is shaped to reduce the pressure developed at the interface between the bony prominence and its

corresponding soft tissue layer for reducing the pressure that would cause a pressure ulcer to develop in that part of the body;

wherein the protective device is shaped to increase the area over which the weight at the bony prominence is distributed as a function of the distance from the bony prominence to the support surface; and

~~The prosthesis as claimed in claim 3~~ wherein the support structure may be one of: a horizontal surface having a wide range of firmness on which a human body is to rest, a mattress having a wide range of firmness, a seating structure, and any prosthetic used to replace a body part.

24. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bony portion surrounded by a soft tissue layer between the bony portion and an outer skin layer and wherein, when the body part is in contact with a support surface, wherein the bony portion tends to concentrate the weight of the part within a relative small region defining a pressure cone, and the weight of the body part including the bony portion ~~may tending to~~ causes a pressure gradient to be developed at the interface between the bony portion and ~~the~~ its underlying soft tissue layer, across the soft tissue layer and between the outer skin layer and the support surface ~~and which~~ may cause a pressure ulcer to develop in the body part, where the pressure at any point is a function of the

weight applied at a the point divided by the area over which the weight is distributed, the prosthesis comprising:

a protective device to be applied to the body part to be protected and placed between the body part containing the bony portion and the support surface; said protective device having ~~an~~ a top, inner, surface conforming to the body part to which it is applied and having ~~an~~ a bottom, outer, surface suitable for making contact with the support surface and generally conformable to the shape of the support surface for transferring the force due to the concentrated weight of the body part over a wider area than said small region; and said protective device having a thickness of a least one quarter of an inch and extending continuously from the region of the body part containing the bony portion to the support surface and the shaped- of said protective device being a function of the shape, size and weight of the body part and the bony portion for increasing the effective area and volume over which the concentrated weight present at the interface between the bony portion and its surrounding soft tissue layer is distributed ~~and for distributing the weight of the body part and of the bony portion over the increased effective area and volume~~ and thereby reducing the pressure due to the bony point exerted at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in contact with the support surface.

25. (newly added) the prosthesis as claimed in claim 24, wherein the top surface of the pad is sculpted to conform to the shape of the body part to be protected for enabling the body part containing the bony prominence to be positioned within the sculpted region and for increasing the surface area over which the weight of the body part and the bony prominence is distributed.
26. (currently amended) The prosthesis as claimed in claim 24 wherein the material between the top and bottom surfaces of the protective device is of the type which enables the inner surface to conform to, and surround, the body part containing the bony prominence for causing the weight of the body part to be distributed over a greater area; and wherein the protective device is placed around the body part to protect the body part regardless of the orientation of the body part on the support surface.
27. (currently amended) The prosthesis as claimed in claim 24 wherein the protective device is comprised of a generally rectangular cushion having a width of at least one quarter(1/4) of an inch and a length of at least one quarter (1/4) of an inch and the material between the top and bottom surfaces being one of an elastic material, a mushy foam, a mesh material, and materials including, but not limited to, dressings, fibrous absorbents, fat-like substance such as silicon or wax, fleeces, foam, gauze, gels, hard shell conforming materials, hydrocolloids, moisture absorbing materials, moisture removing materials, permeable materials, materials which may change in thickness and stiffness, viscoelastic materials and a combination of the above.

28. (previously amended) The prosthesis as claimed in claim 24 wherein the protective device is comprised of a generally semi-cylindrical sleeve.

29. (previously amended) The prosthesis as claimed in claim 24 wherein the protective device is comprised of a generally oblong cushion with a depression located opposite to the bony portion.

30. (previously amended) The prosthesis as claimed in claim 24 wherein the protective device includes means for attaching the prosthesis to the body part.

31. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bony portion surrounded by a soft tissue layer between the bony portion and an outer skin layer and wherein, when the body part is in contact with a support surface, the weight of the body part including the bony portion may cause a pressure gradient to be developed at the interface between the bony portion and the soft tissue layer, across the soft tissue layer and between the skin layer and the support surface and may cause a pressure ulcer to develop in the body part, the prosthesis comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support surface; and said protective device for distributing the weight of the body part and of the bony portion over an extended area and volume for effectively increasing the area and volume of the pressure cone and thereby reducing the pressure due to the bony point exerted at the interface between the bony portion



and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in contact with the support surface;

wherein the bony portion tends to concentrate the weight of the body part within a small region and wherein the protective device functions to increase the area and volume over which the weight is distributed; and.

~~The prosthesis as claimed in claim 24~~ wherein there is included a layer of dressing between the outer skin layer and the inner surface of the protective device.

32. (previously amended) The prosthesis as claimed in claim 24 wherein there is included a layer between the outer skin layer and the outer surface of the pad like structure to allow the skin to breathe.

33. (currently amended) The prosthesis as claimed in claim 24, wherein the body part to be protected is includes at least one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the protective device conforms to its respective body part.

34. (previously amended) The prosthesis as claimed in claim 24 wherein the thickness of the protective device may be selectively increased by adding layers to the outer surface of the protective device for further decreasing the pressure at the interface between the bony portion and its surrounding soft tissue layer.

35. (currently amended) A prosthesis for protecting a part of the human body from developing a pressure ulcer, or for healing an existing pressure ulcer, comprising:

said body part to be protected including a bony portion with a surrounding soft tissue layer between the bony portion and an outer skin layer, and wherein, when the body part is in direct contact with a support surface, the bony portion tends to concentrate the weight of the body part and the bony portion over a relative small area and volume causing pressure to be developed at the interface between the bony portion and the soft tissue layer, across the soft tissue layer, between the soft tissue layer and the outer skin layer and between the outer skin layer and the support surface which is a function of the weight of the body part divided by the area over which the weight is distributed and the thickness of the soft tissue layer, and wherein when the pressure exceeds a certain critical value ( $P_c$ ), pressure ulcers may develop within the body part;

a protective structure enclosing the bony portion of the body part to be protected and located between the bony portion of the body part to be protected and the underlying support surface; said protective structure functioning as an extension of the soft tissue layer surrounding the bony portion and having an inner surface conforming to the body part which it encloses and having an outer surface suitable for making contact with the support surface and being generally conformable to the shape of the support surface for distributing the weight of the body part and the bony portion over a large area; and said protective structure having sufficient

thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin is less than the critical value of pressure ( $P_c$ ) that would cause a pressure ulcer to develop in that part of the body; and wherein the protective structure is shaped to enclose the region of the body part containing the bony portion to increase the surface area at the interface between the bony portion and its surrounding soft tissue layer and across the soft tissue layer and between the soft tissue layer and the outer skin layer and between the outer skin layer and the support structure over which the concentrated weight is distributed for decreasing the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin below the critical value of  $P_c$ .

36. (previously amended) The prosthesis as claimed in claim 35 wherein the critical pressure causing a pressure ulcer is a function of the length of time a given pressure is present, and wherein selected properties of the protective structure applied to the body part, including its size, softness and thickness, are selected to have different values as a function of the length of time the body part is to be on the support surface.

37. (cancelled).

38. (currently amended) The prosthesis as claimed in claim 35, wherein selected properties of the protective structure are selected so as to change gradually as a function of time to gradually increase the area and volume over which the concentrated weight is distributed in order to gradually reduce the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin ~~to~~ of the body part to which it is applied.

39. (currently amended) The prosthesis as claimed in claim 35, wherein selective characteristics of the protective structure including at least one of its thickness, softness, area, volume and compression modulus are selected so as to undergo change as a function of time for increasing the effective surface area and decreasing the pressure applied to the body part components.

40. (currently amended) A protective device for protecting a part of a human body, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to rest upon a support surface, comprising:

a pad to be applied between ~~to~~ the body part to be protected, ~~between the body part and the support surface~~; said pad having: (a) an inner surface conforming to the body part to which it is applied, said inner surface being characterized in that it includes one of the following (i) a cut out to conform to the shape of the body part to be protected for enabling the body part

containing the bony prominence to be positioned within the cut-out region;  
and (ii) a material and shape which enables the inner surface to conform to,  
and surround, the body part containing the bony prominence; and (b) having  
an outer surface suitable for making contact with the support surface and  
being generally conformable to the shape of the support surface for  
effectuating the transfer of the weight of the body part over a large area; ~~and~~  
~~said pad for distributing the weight of the body part over an extended area~~  
~~and volume~~ in order to reduce the pressure exerted between the bone  
structure within the body part and its corresponding soft tissue layer, across  
the corresponding soft tissue layer and at the interface between the  
corresponding soft tissue layer and the corresponding outer skin layer and  
between the corresponding outer skin layer, the pad and the support surface;

wherein the bone structure includes a bony prominence tending to  
concentrated the weight,  $W$ , of the bone structure and overlying body part;  
~~defined as  $W$~~ , over a relatively small area, defined as  $A_1$ , causing a pressure of  
 $P_1$  equal to  $W/A_1$  at the interface between the bony prominence and its  
underlying soft tissue layer, where the body part is in direct contact with the  
support surface; and

wherein the pad surrounds the region of the body part containing the bony  
prominence and is located between the body part and the support surface to  
cause the effective area between the bony prominence and its underlying soft  
tissue layer to be equal to  $A_2$ , where  $A_2$  is greater than  $A_1$ , whereby the resulting  
pressure between the bony prominence and its underlying soft tissue layer is  $P_2$

which is equal to  $W/A_2$ , where  $P_2$  is less  $P_1$ ; and the protective device is selected to make  $P_2$  have a value below a critical value which would tend to cause ulcers in the body part.

41. (withdrawn) A method for protecting selected body parts from developing pressure ulcers or for healing an existing pressure ulcer comprising the steps of:

ascertaining the body parts of an individual prone to the development of pressure ulcers when the individual is placed on a support surface; and

as to each body part ascertained to be prone to the development of a pressure ulcer applying to each different part a protective device having an inner surface conforming to the body part and having an outer surface suitable for making contact with the support surface for enabling the weight associated with each one of said body parts to be distributed over an extended area and volume.

42. (withdrawn) The method as claimed in claim 41, wherein the step of ascertaining the body parts prone to the development of pressure ulcers includes the step of ascertaining at least one of the following: the height, weight, skeletal dimensions of the individual, dimension of body part, weight of body part, contour of body part and shape of the body of the individual and the age, gender level of continence, nutritional status, presence of diseases and state of mind of the individual.

43. (withdrawn) The method as claimed in claim 42 wherein body parts of concern include a bony prominence with a soft tissue layer between

the bony prominence and the outer skin and wherein the step of ascertaining whether a body part is prone to developing a pressure ulcer includes ascertaining at least one of the following: the thickness of the soft tissue, its behavior in compression, its behavior in shear, its behavior in tension, its behavior in friction, and the moisture level of the outer skin layer.

44. (withdrawn) The method as claimed in claim 41 further including the step of placing the individual on a support surface; and wherein the step of applying a protective device to each different part protects the different body parts regardless of the nature of the support surface.
45. (withdrawn) The method as claimed in claim 44 wherein the step of applying a protective device includes attaching a protective device to a selected body part, each protective device placed between the support surface and the body part to be protected, each protective device having an inner surface conforming to the body part to which it is attached and having an outer surface suitable for making contact with the support surface; each protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin

and the support surface is less than a critical value of pressure ( $P_c$ ) that would cause a pressure ulcer to develop in that part of the body.

46. (withdrawn) The method as claimed in claim 41, wherein applying a protective device to each different body part includes ascertaining the thickness of the soft tissue layer of a selected body part and placing a pad between a selected body part and the support surface such that the pressure developed across the soft tissue layer of the corresponding body part is below a certain level.
47. (withdrawn) The method as claimed in claim 46, wherein a portion of the protective device is formed to have one of the following shapes: rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and a combination thereof.
48. (withdrawn) The method as claimed in claim 47, wherein said pad is for distributing the weight of the body part over an extended area and volume and for reducing the pressure at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and a support structure is less than the pressure that would cause a pressure ulcer to develop in that part of the body.
49. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining various characteristics of an individual to be outfitted with



protective devices includes the step of performing at least one of the following: invasively measuring the thickness of the soft tissue layers, non-invasively measuring the thickness of the soft tissue layers, and wherein the step of applying a protective device includes the step of selecting the prosthesis best suited for the person's body part in order to heal an existing pressure ulcer or to prevent the development of one.

50. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining the thickness of the soft tissue layer includes measuring the thickness of the soft tissue layer using at least one of the following: X-rays, CAT scans, MRIs, ultrasound, any suitable diagnostic tool.

51. (withdrawn) A kit of protective devices for protecting a selected number of different body parts of a person from developing a pressure ulcer or for healing an existing pressure ulcer, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the kit comprising:

a set of different protective devices to be applied to respective body parts to be protected, each protective device having an inner surface conforming to the

body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

52. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of different sized protective devices for the same body part in order to fit persons of different sizes.
53. (withdrawn) The kit of protective devices as claimed in claim 51 including a protective device for at least one of the following body parts: heel, trochanter, ankle, knee, sacrum, coccyx, ischium, scapula, elbow, buttocks and occiput.
54. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of pads of predetermined thickness which can be attached to the outer surface of selected protective devices for increasing the thickness of the protective device applied to a body part.
55. (withdrawn) The kit as claimed in claim 51 wherein the protective devices include a series of protective devices for a particular body part where the thickness of each prosthesis is different to enable the selection of a more optimum protective device for the needs of a particular person.
56. (withdrawn) The kit as claimed in claim 51 including a series of protective devices for the same body part having different degrees of

softness for enabling the selection of a more optimum protective device to meet the needs of a particular person.

57. (withdrawn) The kit as claimed in claim 51 further including wound dressing to provide pressure relief and wound care within the same protective unit.
58. (withdrawn) The kit as claimed in claim 51 further including means for shaping selected protective devices for enabling more precise fitting of the device to the body of a person where better contact is required.
59. (withdrawn) The kit as claimed in claim 51 further including means for adding layers to the inner surface of selected protective devices for protecting the outer skin of the person fitted with a protective device.
60. (withdrawn) The kit as claimed in claim 51, wherein each protective device includes at least one of the following:
- a. a dressing;
  - b. a medicated dressing
  - c. a hydrocolloid dressing;
  - d. a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
  - e. a hydrogel;
  - f. a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

- g. a thin film dressing;
- h. a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- i. a gauze dressing;
- j. a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- k. a non woven-dressing;
- l. a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- m. a foam dressing;
- n. a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- o. a material adapted to absorb any excess moisture and drainage;
- p. a material which exhibits moisture vapor permeability; and
- q. a material which exhibits permeability to air for enabling air circulation;

- r. a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance; and
- s. material including therapeutic components such as growth factors and wound healing accelerators.

61. (withdrawn) A garment adapted to protect a selected number of different body parts of a person, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the garment comprising a selected number of sections corresponding to said selected number of body parts to be protected; each one of said sections for securing a protective device at a location corresponding to the location of the body part to be protected; and each protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

62. (withdrawn) The item of attire as claimed in claim 61, wherein the protective devices are secured to the body of the person regardless of movement of the person.

63. (withdrawn) The item of attire as claimed in claim 62, wherein the sections of the item of attire includes flaps for enabling the selective insertion and removal of protective devices.

64. (withdrawn) The item of attire as claimed in claim 61 for securing selected protective devices to selected body parts regardless of the orientation of the body of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

65. (withdrawn) A system for protecting a selected number of different body parts of a person, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part;

means for applying a protective device to selected ones of the body parts to be protected; each such protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for

reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer; and a garment to be placed over at least one body part, said garment having sections located at sites corresponding to the locations of the body part to be protected and said garment adapted to be placed over, at least, a portion of the body of the person for securing at least one protective device to the body part to be protected.

66. (withdrawn) The system as claimed in claim 65 for securing selected protective devices to selected body parts regardless of the orientation of the body of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

67. (currently amended) A prosthesis for healing a preexisting pressure ulcer or protecting a body part from developing a pressure ulcer, where the body part includes a bone with a bony prominence and [,] where the bony prominence tends to concentrate the weight of the body part over a small region whereby there is substantial pressure developed at the interface between the bony prominence and the soft tissue layer, includes a bone to soft tissue interface pressure reducing structure implanted at the site of the bony prominence which pressure reducing structure functions to increase the contact area between the bony prominence and the surrounding soft tissue and thereby causes the weight due to the body part and the bony prominence to be distributed over a larger contact area with the soft tissue and to thereby decrease the pressure to which the soft tissue is exposed.

68. (previously amended) The prosthesis as claimed in claim 67, wherein the bone to soft tissue interface pressure reducing structure is a pad inserted between the bony prominence and its surrounding soft tissue layer and which is fabricated from a material of similar or greater firmness to that of the bony prominence and which behaves in a similar manner to the bony prominence.

69. (previously amended) The prosthesis as claimed in claim 67, wherein the bone to soft tissue interface pressure reducing structure is fabricated from a material of similar or less firmness to that of the soft tissue and which behaves in a similar manner to the soft tissue layer in diffusing the weight between the bony prominence and the actual soft tissue layer.

70. (previously amended) The prosthesis as claimed in claim 67, wherein the bone to soft tissue interface pressure reducing structure is a pad fabricated from a material having a firmness varying from that of the bony prominence to that of the soft tissue and to a firmness softer than that of soft tissue.

71. (previously amended) The prosthesis as claimed in claim 67, wherein the bone to soft tissue interface pressure reducing structure is a pad fabricated from a material enabling the growth of at least one of new bone, new cartilage and new soft tissue in the region between the original bony prominence and the original soft tissue layer.

72. (previously amended) The prosthesis as claimed in claim 70, wherein the pad material includes substances which serve as a matrix and seeding



structure for the formation of new bone or new soft tissue or any suitable new matter.

73. (previously amended) The prosthesis as claimed in claim 67, wherein the bone to soft tissue interface pressure reducing structure is a pad formed of a fatty like substance which exhibits little, if any, dimensional change as a function of time.

74. (original) The prosthesis as claimed in claim 73, wherein the fatty substance may be one of silicone and wax which exhibit little dimensional change as a function of time.

75. (previously amended) The prosthesis as claimed in claim 67 wherein the bone to soft tissue interface pressure reducing structure is a pad formed of material having a first volume when first implanted and which expands to a predetermined size after implantation.

76. (previously amended) The prosthesis as claimed in claim 67 wherein the bone to soft tissue interface pressure reducing structure is made of a material which dissolves over time.

77. (previously amended) A protective device for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure with a bony prominence tending to concentrate the weight of the body part over a small region and a soft tissue layer between the bony prominence of the bone structure and an outer skin layer intended to be in contact with a support structure such that there is an undesirable high pressure at the interface

between the bony prominence of the bone structure and the soft tissue layer, across the soft tissue and outer skin layers and at the interface between the outer skin layer and the support structure, when the body part is directly situated on the support structure, the protective device comprising:

a hard shell-like structure of limited size to be applied to the area of the body part containing the bony prominence; said hard shell-like structure having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; said shell-like structure for distributing the weight of the body part over an extended area and volume such that the pressure exerted at the interface between the bony prominence of the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and a support structure is less than the pressure that would cause a pressure ulcer to develop in that part of the body; and wherein the shell-like structure is shaped to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer below a predetermined level and is of limited size to enable the protected body part to move freely in all directions which the body part can move in the absence of the protective shell-like structure.

78. (cancelled)

79. (previously amended) A protective device as claimed in claim 77, wherein the body part to be protected is at least one of the heel, trochanter, knee, sacrum, coccyx, ischium, scapula, elbow, ankle, buttocks and occiput; and wherein the inner surface of the shell-like structure conforms to its respective body part.

80. (original) A protective device as claimed in claim 79, wherein the inner surface of the shell-like structure includes a soft inner liner.

81. (original) A protective device as claimed in claim 79, wherein the outer surface of the shell like structure is covered with a soft material to prevent damaging or pressuring any other body parts.

82. (original) The protective device as claimed in claim 79 wherein the hard shell like structure is shaped to contour the body part to be protected and reduce pressure on the body part without immobilizing the body part.

83. (withdrawn) A protective device for protecting a part of a human body from developing an ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a relatively firm mold to be applied to the body part to be protected; said relatively firm mold having an inner surface conforming generally to the body part to which it is applied and having an outer surface suitable for making contact with the support structure;

applying an expandable material between the outer skin of the body part to be protected and the inner surface of its corresponding relatively firm mold, said expandable material expanding as a function of the absorption of fluid as a function of time.

84. (withdrawn) The protective device as claimed in claim 83, wherein the expandable material may include at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

85. (withdrawn) A method for protecting a part of a human body, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure such that there is pressure at the interface between the bone structure and the soft tissue layer, across the soft tissue and outer skin layers and at the interface between the outer skin layer and the support structure, the method comprising the step of:

applying an expandable material to the outer skin of the body part to be protected, said expandable material expanding as a function of the absorption of fluid as a function of time.

86. (withdrawn) The method as claimed in claim 85 wherein the body

part to be protected is at least one of the heel, trochanter, knee, sacrum, coccyx, ischium, scapula, elbow, ankle, buttocks and occiput; and wherein the expandable material may include at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

87. (currently amended) A protective device for protecting a part of a human body, where the body part includes a bone structure of the type which has undergone amputation and requires a support surface and a soft tissue layer surrounding the bone structure and wherein, when the body part is in contact with a support surface designed to support the bone structure, there is pressure at the interface between the bony portion and the soft tissue layer, across the soft tissue layer, between the soft tissue layer and the outer skin layer and between the outer skin layer and the support surface, comprising:

a pad-like structure to be applied to the body part to be protected and to be placed between the bone structure and the support surface; said pad-like structure having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure surface and generally conformable to the shape of the support surface; and said pad-like structure having sufficient thickness and softness to distribute

the weight of the body part over an extended and increased area and volume such that the pressure exerted against the soft tissue layer is decreased and is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

88. (currently amended) The protective device as claimed in claim 87, wherein the body part to be protected is a body part which has been amputated, and wherein the support structure is a prosthesis, and wherein the pad-like ~~structure~~ is placed between the amputated portion of the body part and the prosthesis.

89. (currently amended) The protective device as claimed in claim 88, wherein the pad-like ~~structure~~ is formed of a soft material.

90. (currently amended) The protective device as claimed in claim 88, wherein the pad-like ~~structure~~ is formed of a hard material.